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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/071,541	05/04/1998	H.-J. SU HUANG	28685	5607

7590 02/24/2006

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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/071,541		HUANG ET AL.	
	Examiner		Art Unit	
	Leigh C. Maier		1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-16 is/are rejected.
- 7) ☒ Claim(s) 17-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1, 8, 9, 13 and 16 have been amended. Claims 17-19 are newly presented. Claims 1-6 and 8-19 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 1-6 and 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han et al (Cancer Res., 1996) in view of Brem et al (US 5,651,986).

Han teaches that AG1478 specifically inhibits the TK activity of Δ EGFR over wt EGFR. See last paragraph and p. 3860, rt col. The reference specifically suggests the use of AG1478 for the treatment of tumors expressing Δ EGFR, including glioma, lung, breast, and cancers of the gynecological system. See p. 3861, beginning at the paragraph bridging the columns and continuing through the end of the reference. The reference does not teach administration in combination with another therapeutic agent that induces/increases apoptosis.

Brem teaches that paclitaxel, vincristine, cisplatin, among others, are known for the treatment of several types of cancer, including ovarian, lung, breast, and glioma. See, for example, col 3, lines 18-50 and col 7, lines 32-49;.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use any therapeutic agent known for the treatment of the cancers taught by Han in combination with AG1478 in the method discussed above for the additive effects.

It would be within the scope of the artisan to select amounts known in the art for said treatment. There has been no demonstration of criticality in the amounts used. It would be further obvious to prepare pharmaceutical compositions and kits to be used for the method.

Allowable Subject Matter

Claims 17-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As noted previously, the instant specification discloses evidence of unexpected results with the combination of AG1478 and cisplatin. However, these data are not commensurate with the scope of the claims, reciting any agent effective to induce apoptosis. Applicant has submitted Johns et al (PNAS, 2003) to demonstrate that the combination of AG1478 and temozolamide (TMZ) has synergistic antitumor activity. Applicant further contends that the alleged difference in mechanisms of these agents demonstrates that the claimed invention is not limited to cisplatin, its chemical structure or its mechanism of action in inducing apoptosis. Although cisplatin and TMZ may not have precisely the same mechanism of action, they both act directly on DNA and are considered alkylating agents. See Eckhardt (Curr. Med. Chem. – Anti-Cancer Agents, 2002) at tables 1 and 2. On the other hand, vincristine and paclitaxel are antimitotics—not to mention all the other mechanism by which apoptotic agents act. See also, Fan (Biochem. Pharmacol.,

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1999). Furthermore, it is known that agents act synergistically with respect to apoptosis in combination with paclitaxel, but not other agents, such as cisplatin. See Zhu et al (Blood Neoplasia, LCM 2005) at abstract.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
February 17, 2006